JUL 27 2001

K012060

510(k) SUMMARY

Submitter

Keith Dunn
Hu-Friedy Mfg. Co., Inc.
3232 N. Rockwell St.
Chicago, IL 60618
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Date Prepared 6/29/01

Device Name

Trade name	Satin Swivel™ Ultrasonic Insert
Common name	Ultrasonic Insert
Classification name	Ultrasonic Scaler

Legally marketed Device to which equivalence is claimed

Hu-Friedy Ultrasonic Scaler Insert	K953919

Description of the device
The Hu-Friedy® brand Satin Swivel™ ultrasonic insert is similar to the predicate device with the addition of a swivel mechanism allowing for ease of rotational movement during dental cleaning procedures.

This device is intended to be used by dental professionals for dental cleaning and periodontal therapy to remove calculus from the teeth.

The Satin Swivel™ ultrasonic insert has essentially the same internal design as the predicate device except for the addition of several stainless steel and resin components. The steel components enable the insert tip to swivel. The two different resin components allow for a positive grip for the dental professional and a smooth cone to tip transition for ease of use.

To determine if the Satin Swivel™ ultrasonic insert performed similar to or better than the predicate device both laboratory and a field evaluation were undertaken. The laboratory tests included cleaning, sterilization, and mechanical life testing. For the field study clinicians were asked to evaluate the inserts as related to scaling effectiveness, vibration, water delivery, swivel function, and grip. The overall conclusion of this evaluation was that both the Satin Swivel™ and the predicate device met their clinical requirements. The clinicians had complete control of the Satin Swivel™ ultrasonic insert and it did not turn on its own while in use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2001

Mr. Keith Dunn
Manager of Regulatory Affairs
HU-Friedy Manufacturing Company, Incorporation
3232 North Rockwell Street
Chicago, Illinois 60618

Re: K012060
Trade/Device Name: Hu-Friedy Brand Satin Swivel Ultrasonic Insert
Regulation Number: 872.4850
Regulatory Class: II
Product Code: ELC
Dated: June 29, 2001
Received: July 2, 2001

Dear Mr. Dunn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K012060

Device Name: Hu-Friedy Brand Satin Swivel Ultrasonic Insert

Indications For Use:

To be used by Dental Professionals for dental cleaning and periodontal (gum) therapy to remove calculus from the teeth.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K012060

Prescription Use √
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)